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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,470	08/22/2003	Ellen Chien	SYR-CATS-5002-C1	9594
32793 7590 05/16/2007 TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121			EXAMINER NASHED, NASHAAT T	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 05/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/646,470	Applicant(s) CHIEN ET AL.	
	Examiner Nashaat T. Nashed, Ph. D.	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,9,12,15,18 and 27-34 is/are pending in the application.
- 4a) Of the above claim(s) 27-29 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4,9 and 12 is/are allowed.
- 6) ☒ Claim(s) 18 and 30-34 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/4/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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The application has been amended as requested in the communication filed March 26, 2007. Accordingly, claims 1, 9, and 18 have been amended, new claims 30-34 have been added, and claims 2, 3, 5-8, 10, 11, 13, 14, 16, 17, and 19-26 have been canceled. Claims 27-29 remain withdrawn from further consideration.

Claims 1, 4, 9, 12, 15, 18, and 30-34 are under consideration.

Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim for the reasons set forth in the prior Office action, mailed September 25, 2006.

In response to the above objection, applicants argue that the two methods have the same steps and that the method of claim 15 comprises additional steps.

Applicants' arguments have been fully considered, but they are found unpersuasive. The method of claim 9 is a crystallization method, whereas the method of claim 15 is directed to a method of structure determination of the protein using the product of the method of claim 9. Thus, claim 15 does not further limit the scope of claim 9.

Claim 32 is objected to because of the following informalities: the word "noon" is presumed to be typographical error and should be non-. Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The phrase "non-crystalline" in claims 31 and 32 does not appear any where in the specification.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New matter rejection:

Claims 31 and 32-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants allege that support for the new claims can be found in paragraph 187 of the specification. Paragraph 187 at

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page 47 and its amendment filed July 13, 2006 does not support a soluble protein of residues 114-331 of SEQ ID NO: 1 in any form. Said paragraph describe the making of the amino acid sequence of SEQ ID NO: 3, which consists of residues 114-331 of SEQ ID NO: 1 fused to glycine His-tag at the C-terminus. The phrase "non-crystalline" does not appear any where in the specification, and therefore, it is considered a new matter.

Claims 18, 30, 33 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth in the prior Office actions, mailed February 6, 2006 and September 25, 2006.

In response to the above rejection, applicants amended claim 18 to identify the characteristic of the protein as soluble, presumably, in aqueous solution, and argue that the claim comply with the written description requirement because it is similar to example 13 of the written description guidelines.

Applicants' arguments filed 3/26/07 have been fully considered, but they are found unpersuasive. The fact pattern in the instant application and those in example 13 of the written description guideline are different. Said example 13-fact pattern, there is no crystal taught or mentioned in the teaching. No one would come reading the fact pattern of example 13 would come to the conclusion that the claim would read on a crystal form. In contrast, the instant application is dedicated to the crystallization of the protein of SEQ ID NO: 3 and using the crystal of the invention to determine the three-dimensional structure by the X-ray diffraction method. Thus, the claim 18 and its new claim 30 are drawn to a genus of crystals, and the specification provides a single species of this genus of crystal. New claims 30, 33, and 34 are included because the specification does not teach or describe the crystallization of a protein consisting of residues 114-331 of SEQ ID NO: 1.

Claims 18, 31, 33, and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons set forth in the prior Office action, mailed February 6, 2006 and September 25, 2006.

In response to the above rejection, applicant states:

"Applicants further submit that the instant application also meets the enablement requirement because, as discussed above, the instant application not only discloses working examples, but also discloses how to make variants. The disclosure, taken in view of the general knowledge, enables a skilled artisan to practice the claimed invention without undue experimentation. As such, the rejection based on lacking of enablement is improper and should be withdrawn."

Applicants' arguments filed 3/26/07 have been fully considered, but they are found unpersuasive. Enablement requires a disclosure sufficient to allow a person of skill in the art to practice the full scope of the claimed invention without undue

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experimentation. The previous Office action sets out a *prima facie* case of non-enablement, explaining by sound scientific reasoning why a person of ordinary skill in the art would doubt that the guidance of the specification would enable practice of the full scope of the claimed invention without undue experimentation. Applicants have presented no evidence or, indeed, any arguments to establish the adequacy of the disclosure to enable the scope of the instant claims. Applicants merely assert that the claims are enabled. Applicants make no effort to explain why they consider the disclosure of one crystal is sufficient enable of any crystal of the protein of SEQ ID NO: 3 or a crystal containing the polypeptide of residues 114-331 of SEQ ID NO: 1. Conclusory statements unsupported by evidence or scientific reasoning are insufficient to overcome the *prima facie* case of non-enablement set out in the previous Office action.

Claims 1, 4, 9 and 12 are allowed.

Substituting the word "soluble" with ---solution of the--- of claim 18 would overcome the rejections of record, and produces a claim well-supported by the specification.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

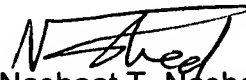
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTWTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen K. Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Nashaat T. Nashed, Ph. D.
Primary Examiner
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